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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/856,320

05/21/2001

Hidetoshi Uemura

UEMURA 4

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07/08/2004

BROWDY AND NEIMARK, P.L.L.C.

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EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 07/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/856,320	Applicant(s) UEMURA ET AL.	
	Examiner Sheridan L. Swope	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30,31,37-41,51 and 58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30,31,37-41,51 and 58 is/are rejected.
- 7) ☒ Claim(s) 30,31, and 37-41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response, on May 4, 2004 to the Final Rejection of this case mailed November 5, 2003, is acknowledged. It is acknowledged that applicants have filed a Request for Continuing Examination. Cancellation of Claims 1-29, 32-36, 42-50, and 52-57, amendment of Claims 30, 31, 37-41, and 51, and addition of New Claim 58 are acknowledged. Claims 30, 31, 37-41, 51, and 58 are pending and are hereby examined.

Specification-Objections***Abstract***

The Abstract is objected to for being a single run-on sentence and for using the legal term "said". Correction is required.

Claims-Objections

Claim 30 is objected to for the phrase "epilepsy in the brain". Epilepsy is a chronic disorder characterized by paroxymal brain dysfunction. Therefore, "in the brain" is redundant.

Claim 31 is objected for lacking parallel sentence construction. Claim 31 comprises a list of possible antibodies in which the first two, monoclonal or polyclonal, are generated to the polypeptide set forth by residues 54-281. But, the third antibody is to a peptide derived from said polypeptide and, furthermore, whether said third antibody is a monoclonal or polyclonal is not recited. For clarity, it is suggested that Claim 31 be revised to state: –The antibody according to claim 30 or an antibody to a peptide fragment derived from a protein consisting of residues 54 to 282 of SEQ ID NO: 2, wherein the antibody is a polyclonal or monoclonal antibody–.

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Claim 39 is objected to. For clarity, an article should be inserted between “of” and “brain” on line 3; i.e. “of the brain”.

Claim 41 is objected to for the phrase “prostatic hypertrophy in the prostate”. Since prostatic hypertrophy is in the prostate, “in the prostate” is redundant.

Claims 37-41 are objected to for being redundant.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Utility

Claims 37-41 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The specification fails to teach a specific and substantial function for the protein set forth by SEQ ID NO: 2, as a diagnostic marker for any specific disease. The specification states “Then, the novel proteases of the present invention are presumed to play various roles in brain, prostate, medulla, lung, placenta, heart, testicle and mucous membrane gland. For example, in brain, there is a possibility that they can be used for treatment and diagnosis of brain diseases such as Alzheimer's disease (AD), epilepsy, brain tumor and the like. Further, in other tissues, there is a possibility that they can be used for treatment and diagnosis of various diseases such as cancer, in particular, prostatic cancer, inflammation, sterility, prostate hypertrophy and the like. Further, it is presumed they may have a certain influence on blood coagulation, fibrinolysis and complement systems.” (page 23, line 20 to page 24, line 8). Such a laundry list of diseases that the protein of SEQ ID NO: 2 might be involved in, is not an assertion of what disease(s) said protein is involved in. The specification fails to positively identify a

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single condition with which the gene/protein is clearly associated; “may be” is not the same as “is”. The specification merely provides unsupported speculation as to numerous conditions that the recited protein might be involved in, but leaves the determination of which of these is correct for others to figure out. Based on the disclosure, one of skill in the art would not be motivated to use the protein set forth by residues 54-282 of SEQ ID NO: 2 as a marker for any disease.

Claims 37-41 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which, the applicant regards as his invention.

Claims 37-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 has two interpretations: (i) the marker consists of the protein of claim 58 or (ii) the disease consists of the protein of claim 58. Clarification is required. For purposes of examination, it is assumed that Claim 37 is meant to recite that the marker consists of the protein of claim 58. If so, a suggested amendment is: A diagnostic marker for detecting a disease, wherein the marker consists of the protein of Claim 58. Claims 38-41, as dependent from Claim 37, are rejected for the same reasons.

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Claims 37-41 are indefinite because it is not clear whether other components are present in the recited marker, such that each of these claims is different, or whether all claims recite the same invention. For purposes of examination, it is assumed that said claims recite the same marker, the protein set forth by residues 54 to 282 of SEQ ID NO: 2.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written description

Claims 30, 31, 37-41, 51, and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Recitation in Claim 58 of a protein consisting of residues 58-282 of SEQ ID NO: 2 represent New Matter, as said protein is not disclosed in the specification or the original claims. Claims 30, 31, 37-41, and 51, as dependent from Claim 58, are rejected for the same reasons.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

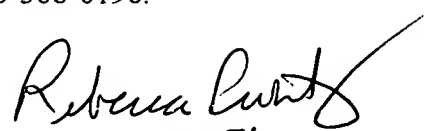
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone

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numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan Lee Swope, Ph.D.


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1800~~
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